

REMARKS

This response is filed in reply to the Office Action mailed October 17, 2007 ("the Action"). Claims 1-27 are pending in the application but stand rejected as being obvious over US 5,908,386 to Ugurbil et al. ("Ugurbil"), in view of US 6,892,089 to Prince et al. ("Prince") and further in view of US 5,431,161 to Ryals et al. ("Ryals"). Applicant respectfully disagrees.

With respect to Claims 1-27, the Action alleges that Ugurbil teaches all the claimed elements except for the use of a stress-inducing agent and that the acquired images are cine loops. Applicant respectfully disagrees (Ugurbil fails to teach or suggest displaying wall motion images with perfusion images at all).

Ugurbil proposes generating T1 weighted images for assessment of myocardial perfusion with contrast agent first-pass kinetics (Abstract). The Action alleges that Ugurbil teaches displaying both wall motion and perfusion images (Action, p.2, para. 3). The Action cites to Col. 9, lines 1-64 and Figures 3A, 4, 5, 7, and 8 in support of this statement. Applicant has reviewed the text at col. 9, but was unable to find any teaching or suggestion of obtaining cines at different heartbeats and displaying wall motion image cines with perfusion image cines. Figure 3A shows the effect of the MDEFT evolution period on image contrast (Col. 8, lines 40-45). Figure 4 shows selected T-1 weighted images (Col. 8, lines 46-55). Figures 5 (Col. 9, lines 19-25); Figure 7 (Col. 9, lines 60-64); and Figure 8 (Col. 10, lines 1-10) also show perfusion images. However, none of these figures show displaying wall motion cines at all, much less displaying them at different heart beat rates or with displaying cine loops of perfusion images with cine loops of wall motion.

Prince

The Action also opines that Prince teaches cardiac motion tracking using cine harmonic phase MRI wherein "differing locations associated with a heart is investigated under dosage of stress inducing agent". Action, p. 3 (citing to Col. 19, lines 50-57, Col. 21, lines 59-64, Col. 24, lines 48-65 and Figure 16a). The Action then alleges that it would have

been obvious to modify a system "similar to that of Ugurbil" so that the screen displays different locations of the heart for a different or single dosage of a stress inducing agent "similar to that of Prince" in order to provide a mechanism to detect heart disease (ischemia) and avoid premature test termination "during the early stages of the myocardial examinations." Action, p. 3. Applicant respectfully disagrees.

Prince fails to resolve the deficiencies of Ugurbil. That is, Prince merely proposes tracking wall motion and determining strain using "tagged MRI" (Col. 5, lines 29-60). Absent the teachings of the instant invention, one of skill in the art would not have combined the references as alleged. Applicant submits that, if properly combinable, a resultant combined system would merely display strain-based wall motion perfusion images, not wall motion cine loops with perfusion images or wall motion cine loops at different heart beat rates with perfusion images.

It will be appreciated that the claimed invention cannot be derived by picking isolated features from various prior art documents as there are technical hurdles associated with generating and displaying the different types of MRI cine loops.

Also, wall motion images are obtained over a single heartbeat (at different heart beat rates) while MRI perfusion images are acquired over several minutes. Embodiments of the instant invention adjust the frame rate of the perfusion cines so that the perfusion cine loops can be temporally synchronized or frames adjusted to be played with wall motion cines for easier visual comparison. Also, the different wall motion cine loops can be temporally synchronized. Furthermore, the temporal synchronization of the cine loops has been found to increase the effectiveness of the evaluation of MRI cine loops as it allows the physician to simultaneously visually compare heart motion at different heart rates where the display heart motion is synchronized to the same portion within the cardiac cycle. Applicant respectfully submits that, even somehow combined in the manner alleged, Ugurbil and Prince fail to teach or suggest such a temporal synchronization as recited, for example, in Claims 1, 13, 20 and 21. Support for this feature can be found in various locations in the pending specification, including pp. 12, 13 and 14 and original Claims 20 and 21.

Ryals

The Action concedes at p. 3, para. 6, that Ugurbil and Prince do not teach that the cardiac imaging system includes a plurality of frames wherein the display simultaneously displays both wall motion cine loops and at least one perfusion cine loop. However, the Action goes on to reject Claims 1, 13-15, 16 and 18-21 as well as Claims 3, 4, 2, 7-11 and 12 in further view of Ryals. To do so, the Action alleges that Ryals teaches "at least one cine loop including frames of perfusion images of at least one cardiac location" and "simultaneously displaying both wall motion cine loops and the at least one perfusion cine loop" (Action, pp. 3-4, para. 7). Applicant again respectfully disagrees.

The Action alleges that it would have been obvious to modify the cardiac display systems to provide the simultaneous wall motion and perfusion cine loops in order to allow "visualization of image frames and also quantitative and qualitative analysis of the image data including segmented functional display illustrating perfusion ratios and wall movement for a selected section of [the] myocardium by a physicians in diagnosing cardiac diseases" ...citing col. 8, lines 56-68 of Ryals (emphasis added).

First, Applicant notes that Ryals issued in 1995 while Prince issued in 2005, 10 years later. However, Prince fails to teach or suggest the simultaneous display of wall motion and perfusion cine loops and merely proposes tagged MRI to evaluate cardiac motion and strain.

Second, Applicant submits that Ryals does not display cine loops of perfusion; rather Ryals calculates a perfusion ratio, which is visually displayed, along with wall motion information (Col. 8, line 65). In contrast, embodiments of the instant invention display perfusion cine loops of MRI images. Also, as noted above, in some embodiments, the frame rate of the perfusion cine loop(s) (which are acquired over minutes, not over one heartbeat) can be adjusted so they can be played along with wall motion cines to allow a clinician to readily visually compare the wall motion and perfusion images for improved safety in stress testing using MRI scanners. Unlike other modalities, in which ECG monitoring can be used for safety monitoring, ECG monitoring is not used MRI scanners. Thus, the instant invention which provides for improved safety in MRI guided stress tests, provides an answer to this

long-felt need.

Further, Ryals is directed to nuclear medicine imaging, *e.g.*, Single Photon Emission Computerized Tomography (SPECT) (a nuclear camera imaging system). Notably, the Ryals patent issued in 1995 while the two MRI-related references issued well after Ryals: Prince issued a decade later and Ugurbil issued in 1999. Neither reference suggests the use of simultaneously displaying the perfusion cine loops with the wall motion cines despite the fact that Ryals was in the public domain. Applicant submits that one of skill in the art would not have combined the teachings of Ryals with that of Prince and/or Ugurbil and that, if obvious, either Prince or Ugurbil would have included the SPECT features in their systems. Also, even if somehow combined, the system would provide perfusion ratios, not perfusion images nor perfusion cines.

Applicant reiterates that MRI and SPECT systems are very different types of imaging systems. Applicant submits that Ryals is not an enabling disclosure for MRI-based cardiac wall motion and perfusion evaluation systems, as the technical operation and image acquisition features of these two different imaging modalities are very different. MRI systems employ certain pulse techniques and breath hold operations and are subject to image distortions and other non-trivial differences that can make stress testing in such a scanner more challenging, particularly where real-time or near-real time image display and acquisition are used (*see, e.g.*, Claims 22 and 23) for improved patient safety. Further, Applicant respectfully submits that the generation, registration and/or synchronization of the different image types for concurrent display allows improved diagnostic data without introducing significant artifacts or distortions (*see, e.g.*, p. 13 of the pending application). One of skill in the art would not have combined the references as alleged to modify the perfusion image system of Ugurbil with the tagged tracking of Prince and the nuclear medicine SPECT system of Ryals to arrive at the claimed invention, absent the teachings of the present invention.

The Independent Claims

Applicant is restating the independent claims below for ease of discussion.

1. A method of displaying cardiac information of a patient having a

cardiac cycle, comprising:

obtaining a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops including cine loops including frames of wall motion images at different heart beat rates and at least one cine loop including frames of perfusion images of at least one cardiac location;

synchronizing images in the wall motion cine loops so that heart motion at the different heart beat rates corresponds to the same portion of the cardiac cycle and adjusting the at least one perfusion cine loop to have the same number of frames as the wall motion cine loops; and

simultaneously displaying both wall motion cine loops and the at least one perfusion cine loop.

5. A method of displaying cardiac information of a patient, comprising:

obtaining a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops including cine loops including frames of wall motion images and at least one cine loop including frames of perfusion images of at least one cardiac location;

synchronizing the MRI wall motion cine loops to concurrently display images corresponding to the same portion of a cardiac cycle of the patient; and

simultaneously displaying both the wall motion cine loops and the at least one perfusion cine loop,

wherein simultaneously displaying comprises simultaneously displaying a plurality of cine loops for differing locations associated with the heart of the patient for a single dosage of a stress inducing agent.

6. A method of displaying cardiac information of a patient, comprising:

obtaining a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops including cine loops including frames of wall motion images and at least one cine loop including frames of perfusion images of at least one cardiac location;

synchronizing the MRI cine loops to concurrently display images corresponding to the same portion of a cardiac cycle of the patient; and

simultaneously displaying both wall motion cine loops and the at least one perfusion cine loop,

wherein simultaneously displaying comprises simultaneously displaying a plurality of cine loops for a single location associated with the heart of the patient for differing dosages of a stress inducing agent.

13. A system for displaying cardiac information of a patient, comprising:

means for obtaining a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops including cine loops including frames of wall motion images and at least one cine loop including frames of perfusion images of at least one cardiac location;

means for synchronizing the plurality of cine loops of MRI images of cardiac wall motion so that heart motion at the different heart beat rates is synchronized to the same portion of the cardiac cycle;

means for registering the plurality of wall motion cine loops to the at least one cardiac perfusion cine loop; and

means for simultaneously displaying both wall motion cine loops and the at least one perfusion cine loop.

14. A computer program product for displaying cardiac information of a patient, comprising:

a computer readable medium having computer readable program code embodied therein, the computer readable program code comprising:

computer readable program code configured to obtain a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops including cine loops including frames of wall motion images and at least one cine loop including frames of perfusion images of at least one cardiac location;

computer readable program code configured to synchronize the plurality of cine loops of MRI images of cardiac wall motion so that heart motion at the different heart beat rates is synchronized to the same portion of the cardiac cycle; and

computer readable program code configured to simultaneously display both wall motion cine loops and the at least one perfusion cine loop.

15. A method of displaying cardiac information of a patient, comprising:

obtaining a plurality of MRI cine loops of the heart of the patient at a plurality of heart rates, the plurality of cine loops

including cine loops including frames of wall motion images;
obtaining at least one MRI perfusion image of at least one
cardiac location;
obtaining at least one MRI delayed enhancement image; and
simultaneously displaying the wall motion cine loops, the at
least one perfusion image, and the at least one delayed
enhancement image.

18. A user interface for MRI imaging cardiac stress test evaluation,
comprising:
at least one region configured to display a plurality of
temporally synchronized cine loops of MRI images of cardiac wall
motion at different heart rates; and
at least one region configured to display at least one MRI
image of cardiac perfusion.

Applicant respectfully submits that these independent claims are patentable for at least the emphasized features. Applicant also respectfully submits that the dependent claims are patentable for depending from an allowable base claim and are also independently patentable. *See, e.g.*, Claims 10, 19, 20 and 22-27 the like.

New Claims 28-29

Applicant further submits that new Claims 28 and 29 are patentable over the cited prior art. These new claims are directed to methods and systems that generate and display multiple wall motion cines, as well as at least one perfusion cine(s) and a delayed enhancement image (of necrotic tissue) (*see, e.g.*, p.13, 16 and Figure 5). Applicant respectfully submits that such a claim includes three different image types that are simultaneously displayed.

Real-Time or Near Real-Time Display During a Stress Test

Applicant also respectfully reiterates that, in contrast to conventional post-study systems, embodiments of the invention now provide real-time or near real-time display of registered images during a stress test. MRI/scanning of patients and displaying the resultant images in near real time can be important in clinical environments while a patient is


undergoing a cardiac stress test which improves patient safety and allows for more immediate diagnosis over past systems. Indeed, Applicant believes that all of the other (MRI) systems are post-study analysis tools. To achieve such a system, the inventors developed a novel and non-obvious system that can provide a plurality of co-registered window displays with a substantially real-time effect. Claims 23-27, and new Claims 29 and 30 include this feature. Applicant respectfully submits that at least Claims 23-27 and 29 are patentable for depending from a patentable base claim and also separately patentable for the recitation of this feature.

Claim 30 also recites that the clinician can also rapidly adjust contrast, brightness, gamma or other display level of the baseline cine loop image which is propagated to the other cine loops of the different window displays without adjusting each one separately (*see, e.g.,* Figure 6, p. 16). Such a feature can provide important clinical information in a rapid manner while a patient is undergoing a stress test, which can also increase the safety of the procedure. Applicant respectfully submits that this feature provides further patentability for Claim 30.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,


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